FORMULATION AND *IN-VITRO* EVALUATION OF TRAMADOL HYDROCHLORIDE FLOATING TABLETS

Narendra Palla*, Valluru Rajashekar, Prashanthi Marni, Jithender Mittepalli, K.A Sridhar
East West College of Pharmacy, Rajiv Gandhi University of Health Sciences, Bangalore, Karnataka, India
Email: narenpalla@gmail.com

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ABSTRACT

Tramadol hydrochloride is a synthetic opioid used as a centrally acting analgesic and effective in both experimental and clinical pain. The half-life of the drug is about 5.5 hours and oral dose is 50 to 100 mg every 4 to 6 hours. To reduce the frequency of administration and to improve patient compliance, a sustained-release formulation of tramadol is desirable. The directly compressible floating tablets of Tramadol HCl were formulated using varying amounts of carbopol-934, HPMC K100M, and Hibiscus rosa-sinensis polymers along with other requisite excipients. Sodium bicarbonate was incorporated as a gas-generating agent. The concentration of the polymers increased gradually to attain the optimised formulation. *In-vitro* drug release profile and floatational characteristics of the formulations were determined. The studies indicated successful formulation of gastroretentive compressed matrices with excellent sustained release and hydrodynamic balance. From FTIR studies no interaction was found between the Tramadol HCl and polymers. Comparison of the dissolution profiles of the optimized formulation, with optimal composition of HPMC: *Hibiscus rosa sinensis*; 100:100, with that of marketed formulation indicated analogy of drug release performance with each other. The optimized formulation F10 was found to exhibit first-order kinetics which shows the diffusion along with polymer relaxation and polymer erosion of drug from the tablet.

Keywords: Tramadol HCl; Gastroretentive floating drug delivery systems; Hydro dynamically balanced systems; Hydroxypropyl methyl cellulose; Hibiscus *rosa-sinensis*.

INTRODUCTION

Oral route is the most convenient and extensively utilized route for drug administration among all the routes that have been employed for systemic delivery of drugs via various pharmaceutical products of different dosage forms. Oral route of administration has been received more attention in the pharmaceutical field because of its ease of administration, patient compliance, least sterility constraints and flexible design of dosage forms.¹ Conventional drug delivery system achieves and as well as maintain the drug concentration within the therapeutically effective range needed for treatment only when taken several times a day.³ This results significant fluctuations in drug levels and the drugs that are easily absorbed from gastro intestinal tract have short half life are eliminated quickly from systemic circulation. These drugs require frequent dosing to achieve therapeutic activity. To avoid these limitations, several attempts have been made to develop many novel drug delivery systems (NDDS) that could revolutionize method of medication and provide a number of therapeutic benefits. The most important objectives of these NDDS are:

(a) Preferably a single dose for the whole duration of treatment.

(b) Site specific drug delivery, thus minimizing or eliminating side effects.⁴

These considerations have led to the development of a controlled or sustained delivery system. The main purpose for developing these systems is to release the drug slowly into the gastro intestinal tract (GIT) and maintain an effective drug concentration in the systemic circulation for long time. But these systems have many disadvantages: longer time to achieve therapeutic blood levels, more variation in bioavailability, enhanced first pass effect, and dose dumping.⁵

Gastroretentive drug delivery is an approach to prolong GRT, thereby targeting site-specific drug release in the upper (GIT) for local and/or systemic effects. Gastro retentive dosage form can remain in the gastric region for a longer period and

hence significantly prolong the gastric retention time (GRT) of drugs. Prolonged gastric retention improves bioavailability, and improves solubility of drugs that are less soluble in a higher pH environment.⁹ certain type of drugs could be used as gastroretentive devices. These include drugs that act locally in the stomach, are primarily absorbed in the stomach, are poorly soluble at an alkaline pH, have a narrow window of absorption and degrade in the colon.¹⁰

Gastro retentive drug delivery is an approach to prolong gastric residence time, thereby targeting site-specific drug release in the upper gastrointestinal tract (GIT) for local or systemic effects. Gastro retentive dosage forms can remain in the gastric region for long periods and hence significantly prolong the gastric retention time (GRT) of drugs.⁷

Floating systems or hydrodynamically controlled systems are low-density systems that have sufficient buoyancy to float over the gastric contents and remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time.¹³

Floating drug delivery systems (FDDS) or Hydrodynamically balanced systems have a bulk density lower than gastric fluids and therefore remain floating in the stomach without affecting the gastric-emptying rate for a prolonged period. The drug is slowly released at a desired rate from the floating system and after the complete release; the residual system is expelled from the stomach. This leads to an increase in the GRT and better control over fluctuations in plasma drug concentration. Floating systems was first described by Davis in 1968. FDDS is an effective technology to prolong the gastric residence time in order to improve the bioavailability of the drugs. FDDS are low-density systems that have sufficient buoyancy to float over the gastric contents and remain in the stomach for a prolonged period. While the system floats over the gastric contents, the drug is released slowly at the desired rate, which results in increased GRT and reduces fluctuations in plasma drug concentration.

MATERIALS AND METHODS

Materials

Tramadol HCl was obtained as gift sample from Leo chemicals, Bangalore. HPMC K100M was obtained from SD fine chemicals, Mumbai. Hibiscus *rosa-sinensis* was obtained from Colorcon Asia Pvt. Ltd, Goa. Carbopol was obtained from S.D. Fine Chem. Ltd, Mumbai, India. All other solvents and reagents used were of analytical grade.

Method

Formulation of floating tablets of Tramadol HCl by direct compression method

Floating tablets of Tramadol HCl were prepared by direct compression method employing sodium bicarbonate as gas-generating agent. HPMC K4M, HPMC K100M and Hibiscus *rosa-sinensis*, Carbopol were used as rate controlling polymers. The concentrations of the above ingredients were optimized as shown in table no:7 on the basis of trial preparation of the tablets. All the ingredients were weighed accurately. The drug was mixed with the release rate retarding polymers and other excipients, except Magnesium stearate, in ascending order of their weight. The powder mix was blended for 20 minutes to have uniform distribution of drug in the formulation. Then, Magnesium Stearate was added and mixed for not more than 1 minute (to ensure good lubrication.) About 250 mg of the powder mix was weighed accurately and fed into the die of single punch machinery and compressed using 8mm flat- surface punches. The hardness of the tablets was adjusted at 4-6 kg/cm² using a Monsanto hardness tester.

Post compression parameters

Thickness of Tablets

The thickness of 10 tablets was measured using Vernier calipers. The extent to which the thickness of each tablet deviated from $\pm 5\%$ of the standard value was determined.

Hardness

The hardness of the tablet was determined by Monsanto hardness tester. The tester consists of a barrel containing a compressible spring held between two plungers. The lower plunger is placed in contact with the tablet, and a zero reading is taken. The upper plunger is then forced against a spring by turning a threaded bolt until the tablet fractures. As the spring is compressed, a pointer rides along a gauge in the barrel to indicate the force. The force of fracture is recorded and the zero reading is deducted from it ten tablets from each batch were selected and evaluated, and the average value with standard deviation was recorded.

Friability

The friability of the tablets was determined using Roche friabilator. It is expressed in percentage. 20 tablets were initially weighed and transferred into the friabilator. The friabilator was operated at 25 rpm for four minutes. After four minutes the tablets were weighed again.

Weight variation

Twenty tablets were individually weighed and average weight was calculated. The individual weight was compared to the average weight. The tablets pass the test if not more than two tablets are outside the percentage limit and if no tablet differs by more than two times the percentage limit.

Swelling studies

The extent of swelling was measured in terms of % of weight gained by the tablet. One tablet from each formulation was weighed and kept in petri dish containing 50 ml of 0.1N HCl solution. At the end of specified time intervals tablets were withdrawn from petri dish and excess buffer blotted with tissue paper and weighed

Buoyancy lag time determination and Total floating time

The *in vitro* buoyancy was determined by the floating lag time. The tablets were placed in a 100 ml beaker containing 0.1N HCl. The time required for the tablet to rise to the surface for floating was determined as the floating lag time and further floating duration of all tablets was determined by visual observation.

Drug content uniformity

Accurately weighed quantity of the powder tablet equivalent to 100 mg of the drug was transferred to 100 ml volumetric flask. 50 ml of buffer solution of pH-1.2 was added. Mixture shaken for 10 min, and then the volume was made up to 100 ml with the same buffer solution, mixed solution was filtered through the membrane filter disc with an average pore diameter not greater than 0.45 μ m. 5 ml of the filtrate was diluted to 100 ml with same buffer solution and examined under U.V Spectrophotometry (1800 SHIMADZU, Kyoto, Japan) at 271nm.

In-vitro dissolution study

The Dissolution study was carried out using dissolution test apparatus USP type II. The dissolution medium used was 900 ml of pH buffer 1.2 at 37 $\pm$ 0.5°. The paddle speed was kept at 70 rpm throughout the study. Aliquot of 5 ml was withdrawn at predetermined time interval and equivalent amount of fresh medium was replaced to maintain a constant volume. After each sampling and suitably diluted with buffer, solutions were analyzed spectrophotometrically at 271nm against suitable blank using UV-visible spectrophotometer (1800, Shimadzu, Kyoto, Japan).

Characterization of Tramadol HCl Floating Tablets

Fourier Transform Infrared Spectroscopy (FT-IR)

The samples of pure Tramadol HCl and HPMC k100M, Hibiscus *rosa-sinensis* and physical mixtures with Tramadol HCl were prepared in the form of KBr pellets and subjected for scanning from 4000 cm⁻¹ to 400cm⁻¹ using FT-IR spectrophotometer.

Kinetic Analysis of In-Vitro Release Rates of Floating Tablets of Tramadol hcl

The results of *in vitro* release profile obtained for all the formulations were plotted in modes of data treatment as follows:-

- Zero order kinetic model – Cumulative % drug released versus T.
- First order kinetic model – Log cumulative percent drug remaining versus T.
- Higuchi's model – Cumulative percent drug released versus square root of T.
- Korsmeyer equation / Peppas's model – Log cumulative percent drug released versus log T.

Table 1: Formulations of Tramadol HCl Floating Tablets (in mg) by Direct Compression

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Tramadol HCl	100	100	100	100	100	100	100	100	100	100
HPMC K100M	100	150	200	-	-	-	-	-	-	100
Hibiscus <i>rosa-sinensis</i> mucilage	-	-	-	-	-	-	100	125	150	50
Carbopol	-	-	-	100	150	200	-	-	-	-
MCC	150	100	50	140	90	40	140	115	90	90
Sodium bi carbonate	40	40	40	50	50	50	50	50	50	50
Mg- state	5	5	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5	5	5
Total	400	400	400	400	400	400	400	400	400	400

Figure 1: FTIR spectra of pure Tramadol HCl

Figure 2: FTIR spectra of Tramadol HCl and HPMC K100M physical mixture

Figure 3: FTIR spectra of Tramadol HCl and Carbopol physical mixture

Figure 4: FTIR spectra of Tramadol HCl and Hibiscus rosasinenses physical mixture

Table 2: FTIR Interpretation

Functional groups	Wave Number (cm ⁻¹)			
	Tramadol HCL	Tramadol + HPMC K-100M	Tramadol +Carbopol	Tramadol +Hibiscus rosasinenses
O-H stretching	3306.10	3306.10	3306.10	3301.45
C-H stretching	2929.97	2929.97	2929.97	2929.47
C=C asymmetric stretching,	1923.09	1922.13	1923.09	1923.12
C=O stretching,	-	-	1719.60	-
C=C aromatic stretching,	1606.76	1606.76	1606.76	1607.19
-CH3 bending vibrations	1479.75	1479.45	1462.09	1478.27
O-H bending vibrations	1409.45	1383.97	1409.45	1459.40
C-N stretching,	1288.49	1289.46	1288.49	1288.73
C-O stretching	1242.20	1242.20	1242.20	1241.26
-CH2&C-H bending,	982.76	982.76	982.76	982.25
O-H bending	702.21	702.11	702.21	703.32

Table 3: Data for pre-compression parameters of tablet formulations (F1-F10)

Formulation code	Bulk density (g/cc)	Tapped density (g/cc)	Carr's Index	Hausner Ratio	Angle of repose(°)
F1	0.45±0.045	0.52 ± 0.09	15.60±0.2	1.15±0.02	26.06± 0.31
F2	0.45±0.045	0.50 ± 0.07	12.23±0.6	1.11±0.04	24.58± 0.15
F3	0.44±0.044	0.50 ± 0.09	12.58±0.8	1.13±0.08	25.44± 0.11
F4	0.45±0.045	0.52 ± 0.04	15.19±0.1	1.15±0.06	28.36± 0.13
F5	0.44±0.044	0.52± 0.01	15.48±0.6	1.18±0.08	28.52± 0.19
F6	0.45±0.045	0.51 ± 0.04	13.48±0.8	1.13±0.09	29.32± 0.19
F7	0.51±0.045	0.59 ± 0.04	14.48±0.8	1.15±0.09	28.69± 0.19
F8	0.50±0.44	0.53±0.06	13.28±0.8	1.14±0.07	24.56±0.17
F9	0.44±0.45	0.57±0.03	12.18±0.7	1.13±0.08	26.65±0.16
F10	0.45±0.45	0.55±0.05	12.28±0.8	1.18±0.09	23.23±0.12

Table 4: Data for post compression parameters of tablet formulations (F1-F10)

Formulation Code	Weight Variation	Thickness (mm)	Hardness (kg/cm ²)	Friability (%)
F1	399.43±4.36	3.28±0.20	4.7±0.54	0.72±0.41
F2	400.81±4.02	3.33±0.22	4.4±0.75	0.37±0.42
F3	400.14±3.89	3.28±0.17	4.2±0.45	0.40±0.38
F4	399.53±3.99	3.16±0.05	4.5±0.25	0.46±0.36
F5	401.08±3.49	3.34±0.05	5.3±0.13	0.61±0.34
F6	400.63±2.99	3.25±0.06	4.5±0.13	0.67±0.35
F7	401.23±2.89	3.51±0.18	4.1±0.14	0.63±0.34
F8	399.56±2.85	3.45±0.14	4.8±0.46	0.44±0.42
F9	400.21±3.32	3.28±0.16	5.2±0.23	0.53±0.46
F10	399.83±2.51	3.45±0.15	5.5±0.28	0.48±0.29

Table 5: Data for post compression parameters of tablet formulations (F1-F10)

Formulation Code	Drug content (%)	Floating lag time(sec)	Swelling index (%)	Floating duration (hrs)
F1	99.78±0.24	49	33.32	16
F2	99.70±0.38	45	35.66	16
F3	99.51±0.32	42	30.91	16
F4	99.94±0.21	54	32.33	20
F5	99.42±0.28	57	35.11	20
F6	99.91±0.23	59	38.18	20
F7	99.58±0.24	50	36.55	24
F8	99.48±0.21	44	33.25	24
F9	99.53±0.33	44	32.65	24
F10	99.46±0.36	40	34.55	24

Figure 5: *In vitro* buoyancy studies of Tramado HCl floating tablet

Table 6: Dissolution data of formulation F1, F2, F3, F4, F5, F6

Time (hrs)	Cumulative % of Drug release					
	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
1	4.26	3.16	2.96	1.57	1.31	1.22
2	8.52	7.42	4.33	3.83	2.65	2.25
3	10.26	9.46	8.46	7.48	6.44	7.38
4	12.32	12.12	10.83	10.63	10.82	10.22
5	20.83	19.22	16.94	15.37	15.35	14.25
6	29.44	24.45	22.27	20.89	23.86	20.77
7	40.15	36.05	33.90	32.91	32.97	29.87
8	49.46	45.56	40.43	39.34	39.08	37.18
9	60.52	49.52	49.62	48.04	48.04	45.94
10	69.64	60.44	60.50	58.33	52.08	50.34
11	80.88	71.08	71.19	66.90	58.60	57.59
12	87.16	80.64	79.24	70.63	64.37	62.27
16	95.52	90.57	86.93	75.14	70.00	67.90
20				80.74	76.53	72.51

Figure 6: Comparative *in-vitro* drug release profiles of Tramadol HCl formulations F1, F2, F3, F4, F5, F6

Table 7: Dissolution data of formulation F7, F8, F9, F10 and M

Time (hrs)	Cumulative % of Drug release				
	F7	F8	F9	F10	M
0	0	0	0	0	0
1	2.27	1.37	1.57	2.36	2.16
2	4.44	3.34	3.14	5.21	4.42
3	7.08	7.18	6.08	8.66	8.46
4	10.13	10.04	9.13	14.81	15.12
5	14.76	14.56	13.47	18.52	19.83
6	20.27	19.47	18.47	25.93	26.44
7	32.28	30.28	26.08	34.55	35.05
8	38.49	38.49	33.59	41.25	42.56
9	47.05	46.86	40.86	49.61	50.52
10	57.78	57.98	48.98	61.53	62.44
11	68.62	63.52	53.42	72.36	73.08
12	77.19	70.28	62.19	79.94	80.96
16	81.92	76.02	67.02	84.77	86.57
20	86.63	81.63	71.82	90.78	91.89
24	90.52	85.35	77.63	98.65	98.85

Figure 7: Comparative *in-vitro* drug release profiles of Tramadol HCl formulations F7, F8, F9, F10, M

Table 8: Kinetic values obtained from different plots of formulations (F1-F10, M)

Formulation Code	Zero-order	First-order	Higuchi	Koshermeyer-peppas	
	Regression Coefficient (r^2)	Regression Coefficient (r^2)	Regression coefficient (r^2)	Slope (n)	Regression coefficient (r^2)
F1	0.927	0.957	0.841	1.213	0.943
F2	0.915	0.965	0.837	1.262	0.971
F3	0.905	0.955	0.822	1.349	0.959
F4	0.926	0.916	0.862	1.595	0.991
F5	0.915	0.931	0.884	1.715	0.989
F6	0.935	0.925	0.875	1.718	0.984
F7	0.894	0.894	0.873	1.449	0.972
F8	0.895	0.895	0.881	1.646	0.991
F9	0.892	0.913	0.89	1.549	0.986
F10	0.901	0.911	0.894	1.434	0.993
M	0.906	0.908	0.895	1.504	0.993

The results of kinetic equations applied to dissolution profiles of each batch of tablets from F1-F10, M were determined as follows.

RESULTS & DISCUSSION

The objective of the present study is to formulate GFDDS of Tramadol HCl using natural and synthetic polymers of different viscosity grades in order to prolong drug release and to impart floating properties to the matrix tablet formulations.

Fourier transformer infrared spectroscopy (FTIR)

The FTIR spectra of pure Tramadol HCl, HPMC k100M, Carbopol, Hibiscus rosasininses and physical mixtures with Tramadol HCl are shown in Figure 7 to 13. The FTIR spectrum of pure drug and physical mixture of drug and polymers were studied. The characteristic absorption peaks of Tramadol HCl were obtained at 3306.10, 2929.97, 1923.09, 1606.76, 1479.75, 1409.45, 1288.49, 1242.20, 982.76, 702.21, 3306.10, 2929.97, 1923.09, 1606.76, 1409.45, 1288.49, 1242.20, 982.76, 702.21 cm^{-1} . These peaks also obtained in the spectrum of each physical- mixtures of the drug and the polymers. By correlating peaks of pure drug spectrum with physical- mixtures of the drug and polymers it was found that the drug is compatible with the formulation components.

Pre-compression parameters

Tramadol HCl floating tablets were prepared by direct compression method using 8 mm punch, adjusting the hardness between 4-6 kg/cm^2 . All the formulations were evaluated for bulk density, tapped density, % compressibility, hausner's ratio and angle of repose. The results of % compressibility, hausner's ratio and angle of repose were found to be <15, <1.25 and <30 respectively. These results show that the formulations have very good flow properties.

Post-compression parameters

The tablets were evaluated for weight variation, thickness, hardness, friability, swelling index, floating lag time, floating duration, drug content and *in-vitro* drug release study.

All the formulations passed the evaluation tests and showed comparable satisfactory results.

The thickness of all tablets was found to be in the range of 3.1-3.6 mm and hardness was found to be in the range of 4-6 kg/cm^2 in all the formulations, the MCC and HPMC together showed good binding properties.

Friability & Weight variation

In all the formulations, the %friability was (0.37-0.72) below 1% as per USP. The average weight was found to be 398-402 mg which will be within the given limits. Hence all the tablets were found to show less weight variation. The drug content of all formulations ranged from 99% to 100%, which is within the specified IP limits.

Swelling index

It was found to range from 30% to 38%, which shows that the formulations swell to a certain degree after coming in contact with the simulated gastric medium. Also the swelling index of tablets containing HPMC K100M showed lower % swelling index than that of the tablets with Carbopol because of the fact that the polymer Carbopol is a more viscous in nature. The results of formulations containing both HPMC K100M and Hibiscus *rosa-sinensis* showed more values of swelling index than that of the ones containing HPMC K100M alone because of the fact that the Hibiscus *rosa-sinensis* showed good swelling properties in the later periods of time and that the CO_2 evolved by NaHCO_3 was entrapped by the fast hydrating polymer HPMC K100M, thus

maintaining the tablet integrity for longer periods of time, enhancing the floating duration time to be >16 hrs.

Floating lag time

The floating lag time of all the dosage forms made of HPMC K100M and Carbopol were found to be satisfactory and were <1 min because HPMC is a hydrophilic polymer and that it swells fast when it comes in contact with 1.2 pH acidic buffer. But the tablets made of HPMC K100M showed lesser FLT as its viscosity is less and that the polymer took even lesser time to form a matrix that could accommodate the evolved gas and also the entrapped gas bubbles during compression are more than that or the gas bubbles in matrices of Carbopol, a more viscous polymer. The tablets containing Hibiscus *rosa-sinensis* alone showed longer FLT as the tablets tend to disintegrate due to the fast release of CO_2 gas. HPMC and Hibiscus *rosa-sinensis* were such that the gas released by the bicarbonate could facilitate the floating of the tablets, which was aided by the fast matrix forming polymer (HPMC) and highly viscous gel forming polymer (Hibiscus *rosa-sinensis*) at the later stage of the drug dissolution, which is evident in the tablets showing a floating duration of >24 hrs

In-vitro drug release rate studies

The *in-vitro* drug release of tablets has shown a profound effect on the choosing of the type of polymers and their concentrations. Initially, the drug release using HPMC K100M, Carbopol and Hibiscus *rosa-sinensis* were compared to see how effectively they could retard the drug release. From the %CDR data of all the formulations, the polymer HPMC K100M showed desirable drug release. Hence HPMC was chosen to make the final formulae with modifications using Hibiscus *rosa-sinensis* as a retarding polymer. The additional use of Hibiscus *rosa-sinensis* was taken into account as the hydrophilic polymer (HPMC K100M), although was able to retard the drug release in the initial stage, could not show effective retardation of drug release in the later stage. Hence, in the later stages of dissolution study, the tablets started to release more amount of drug.

The % Cumulative drug release of all the formulations F1-F10 were within the range of 72.51% to 98.65% for 24 hrs. The optimized formulation F10 showed a % drug release of 98.65% for 24 hrs which shows greater release compare to all other formulations.

The % Cumulative drug release of the optimized formulation F10 were compared with the % Cumulative drug release of the marketed tablet which shows that the optimized formulation is having similar % Cumulative drug release.

The release kinetics of all the dosage forms was calculated using zero-order, first-order,

Higuchi and koser-meyer-peppas. All the formulations were found to follow first-order release kinetics. The dissolution data when fitted into Koser-meyer-peppas model, which indicates that the release was governed by diffusion, polymer relaxation, and erosion. When the data was fitted in higuchi model, the formulations showed diffusion type of drug release. The optimized formulation F10 was found to exhibit first-order which shows that the diffusion along with polymer relaxation and polymer erosion of drug from the tablet.

CONCLUSION

Gastro retentive dosage form using HPMC, Carbopol and Hibiscus *rosa-sinensis* was prepared to develop a sustained release tablets that could retain in the stomach for longer periods of time delivering the drug to the site of action, i.e., stomach. The pre-compression parameters of all formulations showed good flow properties and these can be used for tablet manufacture. The post-compression parameters of all formulations were determined and the values were found to be satisfactory. From the drug content and *in-vitro* dissolution studies of the formulations, it was concluded that the formulation F10 i.e. the formulation containing 25% of HPMC K100M, 12.5% of Hibiscus *rosa-sinensis*, 22.5% of Micro Crystalline Cellulose, 12% of NaHCO₃, 1.2% of Magnesium stearate and 1.2% of Talc is the best formulation. As a result of this study it may be concluded that the floating tablets using a combination of two polymers in optimized concentrations can be used to increase the GRT of the dissolution fluid in the stomach to deliver the drug in a sustained manner. The concept of formulating floating tablets of Tramadol HCl offers a suitable and practical approach in serving desired objectives of gastro retentive floating tablets.

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REFERENCES

1. Zaware S.R, Gaikwad P.D, Bankar V.H, Pawar S.P. A Review on Floating Drug Delivery System. Int J Ph Sci 2010; 2(3): 834-47.
2. Gupta S.K, Gupta udit, Omray L.K, Yadav reetesh, Soni V.K. Preparation and characterization of floating drug delivery system of acyclovir. Int J Appl Pharm 2010; 2(3): 7-10.
3. Natasha Sharma, Dilip Agarwal, Gupta M.K, Mahaveer Pr. Khinchi. A Comprehensive Review on Floating Drug Delivery System. Int J Res Pharm & Bio sci 2011; 2(2): 428-41.
4. Garg R, Gupta GD. Progress in controlled gastroretentive delivery systems. Trop J Pharm Res 2008; 7(3): 1055-66. <http://dx.doi.org/10.4314/tjpr.v7i3.14691>
5. Deshpande A. A, Rhodes C.T, Shah N.H. Controlled release drug delivery system for prolonged gastric residence. Drug Dev Ind Pharm 1996; 22: 531-9. <http://dx.doi.org/10.3109/03639049609108355>
6. Amit Kumar Nayak, Ruma Maji, Biswarup Das. Gastroretentive drug delivery systems: a review. Asian J Pharm Cli Res 2010; 3(1): 2-10.
7. Rani SB, Hari VBN, Reddy BA, Punitha S, Devi P, Rajamanickam V. The recent developments on gastric floating Drug delivery systems: an overview. Int J Pharm Tech Res 2010;2(1):524-34.
8. Basak SC, Rao KN, Manavalan R, Rao PR. Development and *in vitro* evaluation of an oral floating matrix tablet formulation of ciprofloxacin. Ind J Pharm Sci 2004;66:313-6.
9. Nur AO, Zhang JS. Captopril Floating and/or Bioadhesive Tablets: Design And Release Kinetics. Drug Dev And Ind. Pharm 2000;26(9):965 – 69. <http://dx.doi.org/10.1081/DDC-100101323>
10. www.drugbank.com
11. www.ebs.tga.gov.au
12. Martindale. The complete drug reference. 33rd ed. London: Pharmaceutical Press 2002:841.
13. Rowe RC, Sheskey PJ, Quinn ME. Guar gum. Hand book of pharmaceutical excipients. 6th ed, RPS publishers 2006; 298-300.

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